

LISTING OF THE CLAIMS

Please amend claim 13, and cancel claim 1, (claims 2-12 were previously cancelled), and add new claims 18-22, as indicated below.

Claims 1-12. (cancelled)

Claim 13. (currently amended) A composition of a purified HMG-CoA reductase inhibitor having a purity of at least 99.7%, the composition consisting of pravastatin sodium salt according to claim 1 and a total level of impurity of not more than 0.3%, wherein the total level of impurity includes a reduced level of at least one impurity selected from the group consisting of:

- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3S)-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3R)-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6R)-1,2-dihydro-b,d,6-trihydroxy-2-methyl-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-1-naphtaleneheptanioic acid monosodium salt,

- (aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxo-2-3-en-butoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,3-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxopentoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt, and
- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-4-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt.

Claim 14. (original) A composition of pravastatin sodium salt according to claim 13, wherein an individual impurity selected from the group consisting of:

- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3R)-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxopentoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt, and

- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-4-hydroxy-1-oxobutoxy)-1-naphtalennheptanioic acid monosodium salt,

is present in an amount of below the limit of determination.

Claim 15. (original) A composition of pravastatin sodium salt according to claim 13, wherein an individual impurity selected from the group consisting of:

- (aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-Hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3S)-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt, and
- (aR,bR,1S,2S,6R)-1,2-dihydro-b,d,6-trihydroxy-2-methyl-1-naphtaleneheptanioic acid monosodium salt,

is present in an amount of below 0.01 % area.

Claim 16. (original) A composition of pravastatin sodium salt according to claim 13, wherein an individual impurity selected from the group consisting of:

- (aR,bR,1S,2S,6S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt, and
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxo-2-3-en-butoxy)-1-naphtaleneheptanioic acid monosodium salt,

is present in an amount of below 0.1 % area.

Claim 17. (original) A composition of pravastatin sodium salt according to claim 13, wherein the impurity (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,3-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxobutoxy)-1-naphthaleneheptanioic acid monosodium salt is present in an amount of below 0.05 % area.

Claim 18. (new) A composition of a purified HMG-CoA reductase inhibitor having a purity of at least 99.7%, the composition comprising pravastatin sodium salt and a total level of impurity of not more than 0.3%, wherein the total level of impurity includes a reduced level of at least one impurity selected from the group consisting of:

- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphthaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphthaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3S)-3-hydroxy-1-oxobutoxy)-1-naphthaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3R)-3-hydroxy-1-oxobutoxy)-1-naphthaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6R)-1,2-dihydro-b,d,6-trihydroxy-2-methyl-1-naphthaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-1-naphthaleneheptanioic acid monosodium salt,

- (aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxo-2-3-en-butoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,3-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxopentoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt, and
- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-4-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt.

Claim 19. (new) A composition of pravastatin sodium salt according to claim 13, wherein an individual impurity selected from the group consisting of:

- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3R)-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxopentoxy)-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt, and

- (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-4-hydroxy-1-oxobutoxy)-1-naphtalennheptanioic acid monosodium salt,

is present in an amount of below the limit of determination.

Claim 20. (new) A composition of pravastatin sodium salt according to claim 13, wherein an individual impurity selected from the group consisting of:

- (aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-Hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3S)-3-hydroxy-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt, and
- (aR,bR,1S,2S,6R)-1,2-dihydro-b,d,6-trihydroxy-2-methyl-1-naphtaleneheptanioic acid monosodium salt,

is present in an amount of below 0.01 % area.

Claim 21. (new) A composition of pravastatin sodium salt according to claim 13, wherein an individual impurity selected from the group consisting of:

- (aR,bR,1S,2S,6S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-1-naphtaleneheptanioic acid monosodium salt,
- (aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxobutoxy)-1-naphtaleneheptanioic acid monosodium salt, and
- (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxo-2-3-en-butoxy)-1-naphtaleneheptanioic acid monosodium salt,

is present in an amount of below 0.1 % area.

Claim 22. (new) A composition of pravastatin sodium salt according to claim 13, wherein the impurity (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,3-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxobutoxy)-1-naphtaleneheptanoic acid monosodium salt is present in an amount of below 0.05 % area.